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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,071	05/15/2002	Christian Bronner	065691-0266	5986

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,071

Applicant(s)

BRONNER ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/17/05; 06/09/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/17/05;06/09/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1-2 are being examined.

Claim 1 seems to be free of prior art and is allowable.

The following are the remaining rejections.

MISCELLANEOUS

1) The response in the cross-mailed response of 12/22/04 are only directed to removing multiple claim dependencies. The claims in 12/22/04 are not considered here, because the claims and arguments in the response of 12/22/04 are not drawn to the claims presently constituted in the response of 05/17/05.

2) The French reference cited on page 9 of the response of 05/17/05 (Mousli et al, 2002, Bulletin du Cancer, 89 (5): 505-516) could not be reviewed, because it is not translated into English.

SEQUENCE RULE

This application still fails to comply with the requirements of 37 CFR 1.821-25 for the following reasons:

1) Figure 9 legend fails to recite sequence identification number for the sequence drawn in figure 9B.

2) In figure 7 legend, it is still not clear that ICBP-59 is composed of which amino acids of SEQ ID NO:2, because the area in grey is not clear in figure 7.

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Applicant is invited to submit a new drawing of figure 7, wherein the area in grey is more obvious, with a proof that the newly submitted figure 7 is the same as the originally submitted figure 7.

3) The specification still contains sequences that are not identified by sequence identification numbers, for example, sequences on p.5 (CCAAT), pp. 10-11, 40, 42-43, 57-58, 61-61.

It is noted that the Examiner has made an effort to point out failure to comply with the sequence rule, however, it is Applicant's responsibility to find and correct all such failure.

OBJECTION

In the claims:

1) Claim 2 is objected to for the use of the abbreviated language "aa".

2) The amendment of claims 1-2 of 05/17/05 is not in a correct format, because it should be the amendment of the amended claims submitted on 12/22/04, and not of the original claims.

In the specification:

1) The amendment of the specification on p.43, starting on line 20, submitted on 05/17/05 is objected to, for the seemingly typographic error "aminoacid sequence".

2) The amendment of the specification on page 43, starting with line 20, filed 05/17/05 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter

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into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

ICBP-59 ("aminoacid sequence aa 263 to 793 of the sequence of SEQ ID NO:2").

Although the figure 7 legend on page 37 recites that the amino acids indicated in grey correspond to ICBP-59, a review of figure 7 does not find a clear grey area within the amino acid sequence of SEQ ID NO:2. Thus it is not clear which amino acids of SEQ ID NO:2 are the amino acids of ICBP-59.

Applicant is required to cancel the new matter in the response to this Office action.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER

Claim 2 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention.

The limitation of "amino acids 263-793" of SEQ ID NO:2, claimed in Claim 2 has no clear support in the specification and the claims as originally filed.

A review of the specification discloses support for various amino acid sequences cited on pages 7-8, or a probe corresponding to amino acids 269-500 (p.46, lines 18-19), or nucleotides coding amino acids 746-793 (p.59, lines 7-8). There is however no mention of "amino acids 263-793" of SEQ ID NO:2.

The subject matter claimed in claims broadens the scope of the invention as originally disclosed in the specification.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Claim 2 is rejected under 112, first paragraph, as lacking an adequate written description of a polypeptide "having" the amino acids 263-793 of SEQ ID NO:2.

Claim 2 is amended to be drawn to a polypeptide "comprising" a polypeptide "having" amino acids 263-793 of SEQ ID NO:2.

Applicant argues that the revised claims obviate the rejection.

Applicant arguments in paper of 05/17/05 have been considered but are found not to be persuasive for the following reasons:

It is noted that the language "having" is reasonably interpreting as having the same meaning as the open language "comprising".

It is also noted that due to the language "comprising" and "having", the claimed polypeptide encompasses unrelated amino acid sequences attached to amino acids 263-793 of SEQ ID NO:2.

It is further noted that there is no disclosure in the specification of a correlation between structure and critical function of the claimed sequence.

The specification discloses that the ICBP-59 protein is a fragment of the full length ICBP-90, wherein the ICBP-59 protein could bind to an inverted CCAAT box (ICB DNA sequence) (from p.41, last paragraph to p. 43). The specification, which is amended on 05/17/05, discloses that the ICBP-59 protein consists of amino acids 263-793 of SEQ ID NO:2 (the amended p.43, paragraph starting with line 20).

It is noted that there is no indication that binding to a CCAAT box alone would be sufficient to confer the critical function of SEQ ID NO:2, such as induction of an increase

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in the level of topomerase II-alpha, which has five inverted CCAAT boxes (specification, p. 51, lines 11-14; Hopfner et al, 2000, of record, abstract, and p. 121, second column, last paragraph, p. 126, second column, lines 15-18, and figure 6 on p. 126), especially in view that there is no indication that CCAAT box regulates the enhancement of expression of a gene containing said boxes, which occurs by binding of a protein to said CCAAT box.

Further, although amino acids 263-793 of SEQ ID NO:2 contains the zinc finger domains consisting of amino acids 310-366, 724-763 (specification, p. 7, lines 9-13), the zinc finger domains only serve as binding to a DNA sequence (specification, p. 11, paragraph before last). There is no indication that the zinc finger alone is sufficient and responsible for increasing the level of topomerase II-alpha or for any other critical function of SEQ ID NO:2.

Similarly, although amino acids 263-793 of SEQ ID NO:2 contains two potential nuclear localization domains, and various sites for phosphorylation by a kinase (specification, p. 7-8), there is no indication that these nuclear localization domains alone or these phosphorylation sites alone are responsible for increasing the level of topomerase II-alpha or for any other critical function of SEQ ID NO:2.

The specification does not describe a genus of polypeptides comprising amino acids 263-793 of SEQ ID NO:2, that would satisfy the standards set out in the example in *Lilly*. The specification only describes a single polypeptide of SEQ ID NO:2. Thus it necessarily fails to describe a "representative number" of such species. In addition, the

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specification fails to describe “structural feature common to the members of the genus, which features constitute a substantial portion of the genus”.

In addition, the specification does not describe a genus of polypeptides having amino acids 263-793 of SEQ ID NO:2, that would satisfy the standards set out in the example in *Enzo*. The specification does not describe relevant identifying characteristics, or functional characteristics, when coupled with a known or disclosed correlation between function and structure”.

Thus one would conclude that Applicant did not have possession of the claimed polypeptide at the time of filing, and the claims do not meet the 112, first paragraph, written description requirement.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Claim 2 is rejected under 112, first paragraph, because the specification while being enable for SEQ ID NO:2, is not enabled for a polypeptide “having” the amino acids 263-793 of SEQ ID NO:2.

Claim 2 is amended to be drawn to a polypeptide “comprising” a polypeptide “having” amino acids 263-793 of SEQ ID NO:2.

Applicant argues that the revised claims obviate the rejection.

Applicant arguments in paper of 05/17/05 have been considered but are found not to be persuasive for the following reasons:

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It is noted that due to the language "comprising" and "having", the claimed polypeptide encompasses unrelated amino acid sequences attached to amino acids 263-793 of SEQ ID NO:2.

It is further noted that there is no disclosure in the specification of a correlation between structure and critical function of the claimed sequence. There is no indication that amino acids 263-793 of SEQ ID NO:2 alone is sufficient to confer a critical function of SEQ ID NO:2, such as increasing the expression of topoisomerase II-alpha, *supra*.

One cannot predict that the claimed polypeptide having amino acids 263-793 has the function or characteristics of SEQ ID NO:2, in view of the unpredictability of protein chemistry, as taught by Bowie, Burgess et al, Lazar et al, all of record, and thus one would not know how to make the claimed polypeptide, such that it would still have the function and characteristics of SEQ ID NO:2, nor how to use the claimed polypeptide.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

July 25, 2005

SUSAN UNGAR, PH.D.
PRIMARY EXAMINER
